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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	13

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/805,217	BRAMS, PETER	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-28 have been canceled.

Claims 29-38 have been added.

2. Claims 29-38 are under examination.

3. The text of those sections of Title 35 U.S.C. code not included in this office action can be foound in a prior Office Action

4. The following Office Action contains some **NEW GROUNDS** of rejection necessitated by amendment.

Rejection Withdrawn

5. The rejection of claim 1 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments to the claims.

6. The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

7. The rejection of Claims under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does

not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the amendments to the claims.

8. The rejection of claims Claims under 35 U.S.C. 102(b) as being anticipated by Maneta-Peyet et al (J. of Immunological Methods 108:123-127, 1988) is withdrawn in view of amendments to the claims.

9. The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Vogt et al (Am J. Obstet Gynecol 177:964-72, 1997) is withdrawn in view of the new grounds of rejection.

10. The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Umeda et al (The Journal of Immunology 143:2273-79, 1989) is withdrawn in view of the new grounds of rejection..

11. The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Rote et al (Clinical Immunology and Immunopathology 66:193-200, 1993) is withdrawn in view of the new grounds of rejection.

12. The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Thorpe et al (U.S. Patent 6,312,694, filed 7/12/99 with priority to 7/13/98) as applied to claims 1-8 above, and further in view of Harlow et al (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 390-91, 591, 592, 599, 601, 605, 608, 1988) is withdrawn in view of the amendments to the claims.

Response to Arguments

13. The rejection of newly added claims 29-38 under 35 U.S.C. 102(e) as being anticipated by Thorpe et al (U.S. Patent 6,312,694, filed 7/12/99 and has priority to 7/13/98) is maintained.

The response filed 8/6/02 has been carefully considured but is deemed not to be persuasive. The response states that Thorpe et al do not disclose nor envision unconjugated monoclonal antibodies against phosphatidyl serine having complement dependent cytotoxic activity against human cells as claimed herein or particularly human or primate antibodies having such activity (see page 3 of response). In response to these arguments, Thorpe et al clearly teaches unconjugated antibodies against PS that have cytotoxic activity which induce complement dependent lysis (see column 8, lines 30-67) and the antibodies can be monkey, human, chimeric, and humanized (see column 11, lines 25-65).

The following are some NEW GROUNDS of rejection

14. Claims 29 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Vogt et al (Am J. Obstet Gynecol 177:964-72, 1997).

The recite an isolated and unconjugated monoclonal antibody that specifically binds phosphatidyl serine and that induces complement dependent cell-mediated cytotoxicity against a human tumor cell.

Vogt et al teach a monoclonal antibody which binds phosphatidyl serine (see page 965, "Monoclonal aPL antibodies") and the antibody is in HEPES. It is inherent that the antibody of Vogt et al would have the claimed properties of induces complement dependent cell-mediated cytotoxicity against a human tumor cell.

It is the Examiner's position that Vogt et al have produced antibodies with the claimed properties. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Vogt et al, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

15. Claims 29 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Umeda et al (The Journal of Immunology 143:2273-79, 1989).

The claims have been described supra.

Umeda et al teach monoclonal antibodies directed against phosphatidyl serine and compositions comprising such in HEPES buffer (see page 2274). It is inherent that the antibody of Umeda et al would have the claimed properties of induces complement dependent cell-mediated cytotoxicity against a human tumor cell.

It is the Examiner's position that Umeda et al have produced antibodies with the claimed properties. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Umeda et al, the

burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

16. Claims 29 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Rote et al (Clinical Immunology and Immunopathology 66:193-200, 1993).

The claims have been described supra.

Rote et al teach monoclonal antibodies directed against phosphatidyl serine and compositions comprising such in PBS buffer (see abstract and page 194). It is inherent that the antibody of Rote et al would have the claimed properties of induces complement dependent cell-mediated cytotoxicity against a human tumor cell.

It is the Examiner's position that Rote et al have produced antibodies with the claimed properties. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed antibody with the antibody of Rote et al, the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Claim Rejections - 35 USC § 103

17. Claims 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rote et al (Clinical Immunology and Immunopathology 66:193-200, 1993), or Umeda et al (The Journal of Immunology 143:2273-79, 1989), or Vogt et al (Am J. Obstet Gynecol 177:964-72, 1997) and further in view of Thorpe et al (U.S. Patent 6,312,694, filed 7/12/99 and has priority to 7/13/98)

Claims 29 and 34 have been described supra. Claims 30-33 and 35-38 recite wherein the antibody is a primate, human, chimeric, humanized.

Rote et al, Umeda et al, and Vogt et al have been described supra. These references do not teach the antibody is a primate, human, chimeric, humanized, this deficiency is made up for in the teachings of Thorpe et al.

Thorpe et al teach anti-phosphatidyl serine antibodies (see column 14, lines 36-41) and the antibodies can be unconjugated and induce complement dependent cell mediated cytotoxicity (column 8, lines 10-67) and the antibodies can be human or humanized or chimeric (see column 11-12) and compositions comprising such in a pharmaceutical acceptable carrier (see column 79, lines 10-32).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a primate, human, humanized, or chimeric antibody of any of Rote et al, Umeda et al, and Vogt et al as taught by Thorpe et al.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a primate, human, humanized, or chimeric antibody of any of Rote et al, Umeda et al, and Vogt et al as taught by Thorpe

et al because Thorpe et al teach assays with detection using an anti-PS antibody and Thorpe et al teach that tumor cells are PS positive and normal cells are negative and the antibodies would be humanized or human or chimeric because it is well known in the art to produce antibodies that are more human like for human therapy and detection.

Although Rote et al, Umeda et al, and Vogt et al do not specifically disclose the claimed properties of the antibodies, it is expected that the antibodies would have the claimed properties and one skill in the art could readily screen for such properties which as taught by Thorpe are important characteristics of the antibodies.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

18. No claim is allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

21. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

SHEELA HUFF
PRIMARY EXAMINER